

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herein. The Examiner is thanked for determining that claims 40-42, in so far as they read upon the compound carbenoxolone, are allowable.

I. THE OBJECTIONS TO THE SPECIFICATION ARE OVERCOME

The Office Action objected to the specification as containing a hyperlink. The objection is traversed. The Amendment herein has removed the hyperlinks, rendering the objection moot. Reconsideration and withdrawal of the objection is respectfully requested. It is respectfully submitted that the amendment herein does not contain new matter as the hyperlinks have merely been replaced with the title of the document available at the link and the name of the organization at whose website the document is available.

II. THE ART REJECTIONS ARE OVERCOME

Claims 40-42 are rejected under 35 U.S.C. §102(b) allegedly being anticipated by Burchardt et al. (WO 97/15298).

The Office Action states that “Burchardt et al. teaches the treatment of acute and chronic inflammatory disorders, such as psoriasis . . . using a glucocorticoid steroid, such as carbenoxolone sodium . . . and an LTD4 receptor antagonist.” Office Action at 4. The Office Action further notes that “Burchardt et al. teaches the concomitant use of an LTD4 receptor antagonist with carbenoxolone sodium” but states that the use of “comprising” in the claims does not “patentably exclude the additional components, such as the LTD4 receptor antagonist of Burchardt et al.” Office Action at 4. Applicants respectfully disagree with the characterization of Burkhardt et al.

Initially, Applicants respectfully remind the Examiner that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure of the claimed invention. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

Applicants respectfully submit that Burkhardt et al. does not meet these requirements.

The present invention is directed towards methods of treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthetic pathway, said disease including psoriasis, comprising administering carbenoxolone to a patient in need thereof.

In contrast, Burkhardt et al. is directed towards a combination of glucocorticosteroids with LTD4 receptor antagonists in medicaments for the treatment of inflammatory disorders, especially of the airways. *See* the abstract of WO 97/15298.

W097/15298 only mentions carbenoxolone sodium on page 2 in a list of 68 different examples of "customary" glucocorticosteroids. Carbenoxolone sodium does **not** appear in the subsequent list of 37 "preferred" glucocorticosteroids also on page 2, nor does it appear in the group of "particularly preferred" glucocorticosteroids noted at the top of page 3. Furthermore, psoriasis is only mentioned on page 6 as one of a long list of "suitable indications" which not only lists specific diseases but also lists umbrella terms covering groups of diseases.

Accordingly, WO 97/15298 cannot be considered to provide an enabling disclosure. One of skill in the art would have no motivation to select carbenoxolone sodium from a list of "customary" glucocorticosteroids and then to select one specific disease, psoriasis, which appears in a long list of diseases, from within a reference that provides no specific teaching as to either the disease or the compound, and which certainly provides no indication that the compound can be used for the treatment of that specific disease. WO 97/15298 simply provides nothing more than a laundry list of compounds and diseases, and without more, it cannot be considered to provide an enabling disclosure for the selection of a single compound to treat a single disease, especially when the compound is conspicuously absent from the identified lists of "preferred" and "particularly preferred" compounds.

Therefore, as WO 97/15298 fails to satisfy both prongs of the test for a rejection under section 102, the rejection cannot stand. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is therefore respectfully requested.

Furthermore, the presence of carbenoxolone sodium and psoriasis on the laundry lists of WO 97/15298 does not render obvious the present claims.

Indeed, in determining whether claims are obvious in view of a reference, it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further still,

“obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, for an obviousness rejection to stand, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Initially, one of skill in the art would have no motivation to look to WO 97/15298 in determining possible treatments for conditions including psoriasis. The present invention is aimed at treating hyperproliferative diseases and diseases associated with photo-ageing, with the goal of avoiding the adverse effects noted with retinoid administration. WO 97/15298 relates to treating inflammatory diseases using LTD4 receptor antagonist and a glucocorticosteroid. One of skill in the art would have no motivation to look to such a reference, regardless of the inclusion of psoriasis in a laundry list of diseases. Without further teaching as to the hyperproliferative skin diseases which are the focus of the present invention, there is no reason why a skilled artisan wishing to treat hyperproliferative skin diseases would turn to a document which clearly states that the most preferred use of the treatments it describes is for inflammatory airway disorders and especially allergic asthma (page 2, lines 1 to 2 and page 1, line 24 of WO97/15298).

Even if one of skill in the art turned to WO 97/15298, no reasonable modification of the reference would allow them to arrive at the present invention. WO 97/15298 contains three distinct lists of compounds: “customary” glucocorticosteroids, “preferred” glucocorticosteroids, and “particularly preferred” glucocorticosteroids. Of these three lists, carbenoxolone sodium appears only on the first; it is not considered a “preferred” or a “particularly preferred” compound. Accordingly, if a skilled person were to turn to WO 97/15298 to attempt to find a treatment for hyperproliferative skin disorders, one would first look to the compounds identified as “particularly preferred.” In demonstrating that claims are obvious, the reference at issue must demonstrate a likelihood of success. It is respectfully submitted that the only likelihood of success that one of skill in the art would identify from within WO 97/15298 would be from the list of compounds identified as being “particularly preferred.” Indeed, the likelihood of success

would diminish with every step downwards amongst the preferred compounds, such that one of skill in the art would have no reason to expect a successful outcome from those compounds contained on the list of “customary” glucocorticosteroids that were not present on the “preferred” or “particularly preferred” lists. As carbenoxolone sodium is only present on the “customary” list, one of skill in the art would have no expectation of success from its use.

Furthermore, one of skill in the art would also look to modify WO 97/15298 based on the preferred diseases disclosed therein. Accordingly, a skilled artisan would look to WO 97/15298 for teachings applicable to the preferred diseases; it is notable that allergic asthma is the most preferred disease, with other inflammatory airway disorders as the next most preferred. One of skill in the art would have no real expectation of success as they worked their way further down the list of disorders, especially as to an ailment such as psoriasis which was provided only in a laundry list within the reference with no additional teachings as to the disease specifically. And, as psoriasis is not at all related to allergic asthma or other inflammatory airway disorders, the likelihood of success would be further decreased.

Indeed, based on the disclosure of WO 97/15298, one of skill in the art would first look to apply the teachings of WO 97/15298 to the particularly preferred glucocorticosteroids first, namely beclomethasone and budesonide, for the disclosed preferred diseases. Thereafter the skilled person might turn to the longer list of preferred glucocorticosteroids spanning page 2, line 24 to page 3, line 1, but one of skill in the art would have no motivation or expectation of success to turn to the list of “customary” glucocorticosteroids. And, certainly one of skill in the art would have no motivation to select carbenoxolone sodium from the “customary” list; nor would one of skill in the art find any motivation in the teachings of WO 97/15298 to try and treat psoriasis with the disclosed compounds since psoriasis merely appears in a shopping list of disorders and no further teachings as to the disorder are provided.

Additionally, it should be noted that WO 97/15298 presents a list of 68 different glucocorticosteroids (at page 2) for use with an LTD4 receptor antagonist and a list of approximately 46 diseases or types of conditions (at page 6). Consequently, one of skill in the art is presented with well over 3,000 possible resulting combinations, with no teachings as to which to select other than to start with beclomethasone and budesonide for the treatment of allergic asthma or other inflammatory airway disorders. After this selection, one of skill in the art is left to their own devices as WO 97/15298 provides no further guidance in making

selections from the provided lists. Accordingly, selection of carbenoxolone sodium for the treatment of psoriasis is nothing more than "cherry picking" from the disclosure of WO97/15298. One of skill in the art would have no motivation to do so, nor would an expectation of success be present. And, there is absolutely no enabling disclosure as to the specific combination of carbenoxolone sodium for the treatment of psoriasis.

Therefore, WO 97/15298 clearly does not anticipate the present invention as it does not contain an enabling disclosure, and, nothing in WO 97/15298 provides the motivation or expectation of success necessary to elevate the selection of carbenoxolone sodium for the treatment of above mere "cherry picking."

Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

For the reasons stated above, applicant respectfully requests a favorable reconsideration of the application, reconsideration and withdrawal of the rejections of and objections to the instant application, and prompt issuance of a Notice of Allowance.

Respectfully submitted,
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